UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,233	02/27/2004	Nicholas V. Perricone	00961-P0247A	7987

24126 7590 03/31/2006

ST. ONGE STEWARD JOHNSTON & REENS, LLC
986 BEDFORD STREET
STAMFORD, CT 06905-5619

EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,233	PERRICONE, NICHOLAS V.	
	Examiner	Art Unit	
	Marcela M. Cordero Garcia	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-11 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the reply received on April 15, 2005.

Any rejection from the previous office action, which is not restated here, is withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant has added new claim 12. Please note that there is a duplicate claim 12, since original claim 12 is currently withdrawn. Accordingly, the secondly presented claim 12 has been renumbered by Examiner to claim 26, in accordance with 37 CFR 1.75(f). Any amendments to the claims should include this correction.

Claims 1, 3-11 and 26 are presented for examination on the merits.

Claim Rejections - 35 USC § 103

Claims 1, 3-11 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hersh (US 6,011,067, cited in the IDS of February 27, 2004) in view of Ulrich et al. (US 5,728,735, cited in the IDS of June 9, 2005).

Hersh beneficially teach a method for the treatment of psoriasis, said treatment comprising topically applying to the affected skin areas a topical composition containing an effective amount of reduced glutathione. (See, e.g., column 11, lines 57-59 and examples 1-3).

Hersh does not expressly teach 16 to 70% glutathione by weight in the composition and/or the composition thereof comprising 0.5-5% alpha-lipoic acid).

Ulrich et al. beneficially teach alpha-lipoic acid as an active ingredient in topical compositions for the treatment of psoriasis. (See, e.g., column 6, line 1 and claims 1-9).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose and for the following reasons: It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 1943 C.D. 518. Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore ipso facto unpatentable. Accordingly, the instant claims, in the range of proportions where no

unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention, especially because Hersh et al. teaches up to 15% of reduced glutathione, which is pretty close to 16%, and in addition mentions no adverse effects for higher concentrations of glutathione, in other words, does not teach away from the invention. The adjustment of particular conventional working conditions (e.g., determining appropriate concentrations of the active ingredients within such compositions) is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Applicant argues that Hersh et al. explicitly teaches a composition requiring the combination of L-glutathione and selenium (Hersh, col. 6, lines 57-62, column 7, line 66-column 8, line 1).

Applicant's arguments have been carefully considered by Examiner, but not deemed persuasive because although selenium is a co-factor for glutathione peroxidases, Hersh et al. also teach that glutathione is a known antioxidant (column 7, lines 23-31) and a detoxifier (column 7, lines 20-31) that do not require selenium. Therefore Hersh et al. do not teach away from using only glutathione. Furthermore, the instant claims do not exclude the use of selenium.

Applicant also argues that Hersh et al. only teach up to 15% by weight of glutathione (column 8, lines 18-19) and therefore Hersh et al. do not suggest, e.g., 16% of glutathione by weight.

Applicant's arguments have been carefully considered by Examiner, yet not deemed persuasive because Hersh et al. do not indicate any negative effects resulting from making a higher concentration cream, e.g., at 16% per weight of glutathione, which is pretty close to the 15% per weight of glutathione.

Applicant also argues that there is no motivation to combine Hersh and Ulrich because Hersh does not disclose alpha-lipoic acid. Applicant's arguments have been carefully considered by Examiner, but not deemed persuasive for the reasons of record.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marcela M Cordero Garcia, Ph.D.
Patent Examiner
Art Unit 1654

MMCG 03/06

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600